

## California's Stem Cell Agency Invests in Phase 3 Clinical Trial to Help Kidney Transplant Patients

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January 18, 2018 - Oakland, CA Over 650,000 Americans suffer from end-stage kidney disease - a life-threatening condition caused by the loss of kidney function. The best available treatment for these patients is a kidney transplant from a genetically matched, living donor. However, patients who receive a transplant must take life-long immunosuppressive drugs to prevent their immune system from rejecting the transplanted organ. Over time, these drugs are toxic and can also increase a patient's risk of infection, heart disease, cancer and diabetes. Despite these drugs, many patients still lose transplanted organs due to rejection.

Reducing or eliminating the need for immunosuppressive drugs in kidney transplant patients is an unmet medical need that the California Institute for Regenerative Medicine (CIRM) is well aware of. Today, CIRM's governing Board announced that it will invest \$18.8 million dollars in a Phase III clinical trial sponsored by Medeor Therapeutics to address this need head on.

Medeor, a biotechnology company located in San Mateo, California, is developing a stem cell-based therapy, called MDR-101, that they hope will eliminate the need for immunosuppressive drugs in genetically matched kidney transplant patients.

"These immunosuppressive drugs not only can cause harmful side effects, but they are also expensive and some patients lose their transplant either because they can't afford to pay for the drugs, or because their effectiveness is not adequate," says Maria T. Millan, M.D., President and CEO of CIRM. "Medeor's stem cell-based therapy aims to prevent transplant rejection and eliminate the need for immunosuppression in these kidney transplant patients. If they are successful, this approach could be developed for other organs including heart, liver, and lung transplants."

The company takes blood-forming stem cells and immune cells from the organ donor and infuses them into the patient receiving the donor's kidney. Introducing the donor's immune cells into the patient creates a condition called "mixed chimerism" where immune cells from the patient and the donor are able to co-exist. In this way, the patient's immune system is able to adapt to and tolerate the donor's kidney, potentially eliminating the need for the immunosuppressive drugs that are normally necessary to prevent transplant rejection.

CIRM funding will enable Medeor to test their stem cell-based treatment in a Phase 3 clinical trial. If the trial meets its objective in allowing patients to eliminate immunosuppressive drug use without rejection, Medeor may apply to the Food and Drug Administration (FDA) for permission to market their therapy to patients in the United States.

"We are very grateful for the financial support and validation from CIRM for the MDR-101 program," said Steven R. Deitcher, M.D., co-founder, President and Chief Executive Officer of Medeor. "CIRM funding accelerates our timelines, and these timelines are what stand between needy patients and potential transformative therapies. This CIRM award combined with investor support represent a public-private collaboration that we hope will make a difference in the lives of organ transplant recipients in California, the entire U.S., and beyond."

This is the fourth clinical trial targeting kidney disease that CIRM's Board has funded. CIRM is also funding a Phase I trial testing a different stem cell-based therapy for end-stage kidney disease patients out of Stanford University led by Dr. Samuel Strober.

| About CIRM |  |  |  |
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At CIRM, we never forget that we were created by the people of California to accelerate stem cell treatments to patients with unmet medical needs, and act with a sense of urgency to succeed in that mission.

To meet this challenge, our team of highly trained and experienced professionals actively partners with both academia and industry in a hands-on, entrepreneurial environment to fast track the development of today's most promising stem cell technologies.

With \$3 billion in funding and approximately 300 active stem cell programs in our portfolio, CIRM is the world's largest institution dedicated to helping people by bringing the future of cellular medicine closer to reality.

For more information go to www.cirm.ca.gov.

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